Lyme Disease Association, Inc. Written Testimony February 6, 2009 to Connecticut Public Health Committee

www.LymeDiseaseAssociation.org

Co-Chairmen Harris & Ritter & Committee Members:

As background: the Lyme Disease Association (LDA), all-volunteer national non profit devoted to education, research, prevention and patient support, is registered in CT and has 32 allied organizations nationwide–in CT, a chapter, an affiliate and two supporter groups. LDA and its CT Affiliate, Time for Lyme, opened the endowed Lyme and Other Tick-Borne Diseases Research Center at Columbia University, the first such center in the world to study chronic Lyme disease. LDA has spoken at many seminars in CT including the University of New Haven Lyme Conferences in 2007 & 2008.

Two weeks ago, I was invited to be part of a 3-day focus group workshop on *Lyme Disease in the South* at the Centers for Disease Control & Prevention in Atlanta, GA. A researcher opened his talk saying the situation with Lyme is "not so bad," then proceeded to show graphs of case numbers in a few states to prove his assertion—including both CT and RI numbers. I pointed out that those examples were flawed, since both those states had changed reporting requirements which caused both states' number to drop or not rise in a manner consistent with prior reporting before the criteria were changed. Misinterpretation of data, unfortunately, can drive resources and focus on a disease; for example, an unknowledgeable observer looking at CT's current 2008 Lyme numbers might think Lyme has been eradicated in CT, since the 2008 reported numbers in CDC's *Mortality & Morbidity Weekly Report* (MMWR, 1-2-09) for CT are zero to date.

According to CDC, from 1990 through 2007, Connecticut had 42,042 reported cases of Lyme disease. CDC states only 10% of cases that meet the CDC surveillance criteria are reported,[i] that means 420,420 Connecticut residents developed Lyme that met the surveillance criteria over 17 years. 2007 numbers showed a 71% increase in CT over 2006 numbers, and the Connecticut Agricultural Experiment Station *Summary of Tick Testing Results* estimates that in Connecticut, "the number of Lyme disease cases reported may represent only 10-20% of diagnosed cases."

Data is often used to marginalize Lyme patients' problems, so it is important that those who shape public policy and laws are able to have access to all the data, not just data which vested interest would like to use to contend Lyme is hard to get and easy to cure. So thanks for allowing me to testify favorably today on physician protection.

Two man-made sets of criteria greatly influence the ability of doctors to treat Lyme patients, the CDC surveillance criteria and the Infectious Diseases Society of America (IDSA) Lyme treatment guidelines. Despite CDC's warning on their website that surveillance case definitions establish uniform criteria for disease reporting and should not be used as: the sole criteria for establishing clinical diagnoses; determining the standard of care necessary for a particular patient; or setting guidelines for quality assurance, or providing standards for reimbursement; the majority of doctors are inappropriately using CDC surveillance criteria to diagnose and treat. Patients who do not meet the CDC surveillance criteria– in an endemic region, an EM rash (plus a required test in a non-endemic region), OR major system involvement plus positive blood work– must scramble to find physicians willing to risk making a clinical diagnosis for Lyme disease. Problems about who has Lyme are fueled by unreliable Lyme testing [ii] and by the fact that less than 50% of people develop the classic bull's eye rash. [iii]

Despite disclaimers that the 2006 IDSA Lyme treatment guidelines are only recommendations **against any long-term treatment for people who are chronically ill with Lyme; against entire classes of antibiotics; against alternative treatments; against some supplements; and against individual physician discretion in diagnosis and treatment**, actual experiences prove otherwise. That is why, to date, almost 40,000 people have signed an LDA petition opposing the IDSA treatment guidelines on humanitarian grounds. (see www.LymeDiseaseAssociation.org)

Due to a settlement with the CT Attorney General, the current guidelines are being reviewed by a newly constituted panel. All Lyme disease treating physicians who applied for a seat on the upcoming panel were denied one, based on having a "conflict" if they made over $10,000 treating Lyme disease. The IDSA has confused helping patients get better with 'real' competing conflicts such as interests in testing and vaccines, and relationships with insurers–a

profile found in the original IDSA guidelines panel. It is like publishing a manual for fixing cars that is written by academics studying about cars rather than by mechanics who are constantly under the hood.

Our Lyme mechanics, the treating physicians, are given that academically produced manual and told it is a guideline for treatment, not law. However, when they do not follow that "guideline," they are scrutinized by their state medical boards, by infectious disease specialists in hospitals and by insurance companies. They may have sanctions placed on their licenses, hospital privileges revoked, may be removed from hospital posts, and may have insurance plan inclusion revoked if they do not march lockstep with IDSA. This has led to a scarcity of physicians and a "chilled" treatment climate nationwide, even worldwide, where Lyme is now found in about 65 countries. CA, CT, MI, NC, NJ, NY, OR, PA, TX, VA are some of the states where physicians who treat long-term have been investigated by state medical boards for treating outside the short term standard of care.

Another set of guidelines for Lyme which address early infection and chronic disease, provide a second standard of care. They are published by the International Lyme & Associated Diseases Society (ILADS), a professional medical and research organization, [iv]and are ignored by IDSA and often not disclosed to patients as part of the principles of autonomy and informed consent. Both IDSA's & ILADS' guidelines have passed the inclusion requirements of being evidenced-based for acceptance on the National Guidelines Clearing House website (NGC) produced by the US Department of Human and Health Services.[v]

Patients who are not diagnosed quickly or not treated appropriately sometimes become chronically ill. A study has shown that patients with Lyme disease suffer a degree of disability equal to that of patients with congestive heart failure.[vi] Yet these patients, often multi-members of one family,[vii] now have to travel many hours outside CT to find care for their Lyme disease. Patients do not have the resources nor the health to fight the vested interests stacked against them, which is why legislation is necessary since it ensures that treating doctors within the state **cannot be** prosecuted for unprofessional conduct just for providing any longer term treatment deemed necessary in the treating physician's clinical judgment.

Development of antibiotic resistance is a reason sometimes cited to withhold treatment, despite the fact that resistance often develops due to **under usage** rather than over usage of antibiotics to eradicate organisms. The Union of Concerned Scientists estimates that 70% of antibiotics in the U.S. are fed to healthy pigs, cows, and chickens to promote growth and prevent disease, and they are concerned quite concerned this may be a significant cause of resistant bacteria.[viii] Recent studies have shown that resistant strains of bacteria most often develop in hospitals due to improper hygiene by medical personnel. Other diseases are allowed long-term treatment including tuberculosis, Q fever endocarditis, and even acne. It appears that with little outcry, animals can be fattened with antibiotics, health care workers can practice shoddy hygiene leading to resistant strains, acne sufferers can get years of treatment, but terribly sick Lyme disease patients are singled out to be left without treatment because of undocumented accusations of resistance due to actual medical treatment.

In closing, CT owes it to its patients and physicians to pass a doctor protection bill, a version of today's bill with some definitions and tightening of protective language, which will simply level the playing field by providing treating physicians with a measure of protection they are entitled to, since there are two standards of care. Doctors should not be penalized for following the standard which in their clinical experience best improves patient health.

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i Meade, Paul, CDC, Herald News 5-4-04, Jessica Adler

ii P. Coulter et al, **J. Clin Microbiol.**. 2005Oct.; 43(10): 5080-4 *Two Year Evaluation of Borrelia burgdorferi Culture and Supplemental Tests for Definitive Diagnosis of Lyme Disease. Lancet 1990, Journal of Clinical Investigation 1994 & S. Schutzer et al, **JAMA** Vol 282, No. 20 Borrelia Burgdorferi: Specific Immune Complexes in Acute Lyme Disease, Nov. 24, '99*

iii R. Smith et al Annals of Internal Medicine 2002;421:421-428, 477-479 ; A. Pachner Reviews of Infectious Diseases-Vol. II, supplement 6 - September-October 1989 Neurologic Manifestations of Lyme Disease, the new "Great Imitator"; J.M. Johnson, Ph.D., Chief, Public Health, NPS Ticks and Disease

iv Expert Review of Anti-infective therapy 2(1) Suppl. 2004

v http://www.guideline.gov/

vi Connecticut Agricultural Experiment Station. "Summary of Tick Testing Results for 2003." www.caes.state.ct.us.

vii CDC unpub. data presented in Congressional forum, Wall NJ Oct 1992 (Later pub. in Lyme Times)

viii http://www.ucsusa.org/food_and_environment/antibiotics_and_food/myths-and-realities

Connecticut Lyme & Tick-Borne Diseases Briefing Paper
by Lyme Disease Association, Inc. (LDA)
www.LymeDiseaseAssociation.org

Lyme disease was first identified in Connecticut in 1975 and continues to be an important public health concern today. The state of Connecticut (CT) has generally been among the top three states with the most reported Lyme disease cases in the country. Surveillance, maintained by the Department of Public Health (DPH), indicates CT has the highest number of cases relative to the population of any state in the nation.

In 2007, CT ranked 4th nationwide in the total number of cases reported to the Centers for Disease Control and Prevention (CDC), showing a rise in cases from 704 in 1990 to 3,058 cases in 2007. Fairfield County reported the most new cases, 470 in 2007, while Litchfield and Tolland reported 206 and 205 cases per 100,000 residents, respectively. (1)

The goal of the US Surgeon General's ten year program, Healthy People 2010, is aimed at reducing the annual incidence of Lyme disease to 9.7 new cases per 100,000 population in 10 reference states (2) where the disease is endemic, which includes Connecticut. According to the CDC in 2007 CT incidence was 87.3 per 100,000 compared to a national total incidence of 9.1

In 2002, the Connecticut Department of Public Health discontinued mandatory reporting of Lyme disease by laboratories. In turn, case numbers dropped from an all time high of 4,631 in 2002 to 1,403 in 2003, a 70% drop in cases on paper. Full lab reporting was not reinstituted, although CT has now gone to electronic reporting, but DPH has said only 2 labs are hooked up. To date for 2008, the Lyme disease reported cases for CT are listed in CDC's MMWR as 0. There were 27, 444 total cases nationwide reported to CDC for 2007 (corrected # by CDC on 9/19/08)

According to the CT Department of Public Health, Lyme disease ranks 2nd out of 69 reportable diseases, trailing Chlamydia, which had the highest total number of reported cases for any disease in the state in 2007. For the first time in 2007, Lyme disease cases in CT surpassed the number of reported cases of Gonorrhea (4), making Lyme not only the most prevalent vector-borne disease in the country, but one of the most formidable infectious diseases in the state of CT.

To understand the ramifications of the numbers, one needs to know that the CDC has indicated that only 10% of the cases that meet its surveillance criteria are actually reported, indicating about 30,580 cases of Lyme disease that met the CDC surveillance criteria occurred in CT in 2007, and 274,440 Americans who fit the surveillance criteria developed Lyme disease nationally. From 1990-2007, 2,929,300 people nationwide met the CDC surveillance criteria for Lyme disease.

No one is tracking the number of Lyme cases that do not meet the surveillance criteria, cases that are physician-diagnosed clinically and the ones that most often develop into chronic disease. Estimates range from 10-15 to 40% of Lyme cases develop into chronic disease (cases that have failed a standard treatment course and continue to be symptomatic). Patients diagnosed with chronic Lyme disease often cannot buy life insurance policies, since they have a chronic disease, yet they cannot get health insurance reimbursement because chronic Lyme "does not exist."

Other tick-borne disease are on the rise in CT and nationally. Babesiosis, carried by the same deer tick, ranked 15th in the state amongst all reportable illnesses in 2007, with 156 total cases; up from 102 cases in 2006. The highest number of reported cases was from New London County

(64). Congestive heart failure, renal failure, and acute respiratory distress syndrome are the most common complications reported in patients with babesiosis. (5) Many cases, however, are asymptomatic or not recognized by health care providers, resulting in a potentially serious threat to patients, as well as the nations blood supply.

After nearly a decade with no reported deaths due to transfusion-transmitted babesiosis, the US Food and Drug Administration (FDA) received 8 reports (CT included) from November 2005 onward. Most of the patients with babesiosis, it reported, developed altered mental status, kidney failure, or respiratory distress, with symptoms appearing anywhere from 2.5 to 7 weeks following a blood transfusion. Once symptoms developed, death followed within 5 to 17 days. FDA officials noted that *Babesia* species, like Lyme, can survive blood banking procedures, including freezing (6).

From 1991 through 2000, 296 cases of babesiosis were reported to the Connecticut DPH. Of these, 67% were reported in residents of New London County. Cases were reported in residents of each county, except Tolland. The mean age of reported case patients was 64 years; 61% were males. Infection was seasonal with 82% being reported in June, July, and August. In Connecticut, where both Lyme disease and babesiosis have been reported, the DPH recognizes the possibility of concomitant babesial infection and indicates it should be considered when moderate to severe LD has been diagnosed.

In 2007, there were 31 confirmed cases of ehrlichiosis (HGE-now called anaplasmosis), with Fairfield County reporting the highest number (11). In 2006, Litchfield County reported nearly half of all ehrlichiosis cases. Cases of ehrlichiosis dropped from 111 reported cases in 2000, to only 29 cases in 2003 when mandatory reporting by labs was discontinued.

In DNA analyses for the agent that causes human granulocytic ehrlichiosis (now anaplasmosis), 50% of 118 adult *I. scapularis* ticks from Connecticut were infected. Although a reportable disease, the number of human cases of tularemia in Connecticut is unknown. (7) Considering many doctors do not look for these co-infections transmitted by the bite of the *Ixodes scapularis* (deer) tick that transmits Lyme disease, these numbers and lack thereof, should trigger concern among CT officials.

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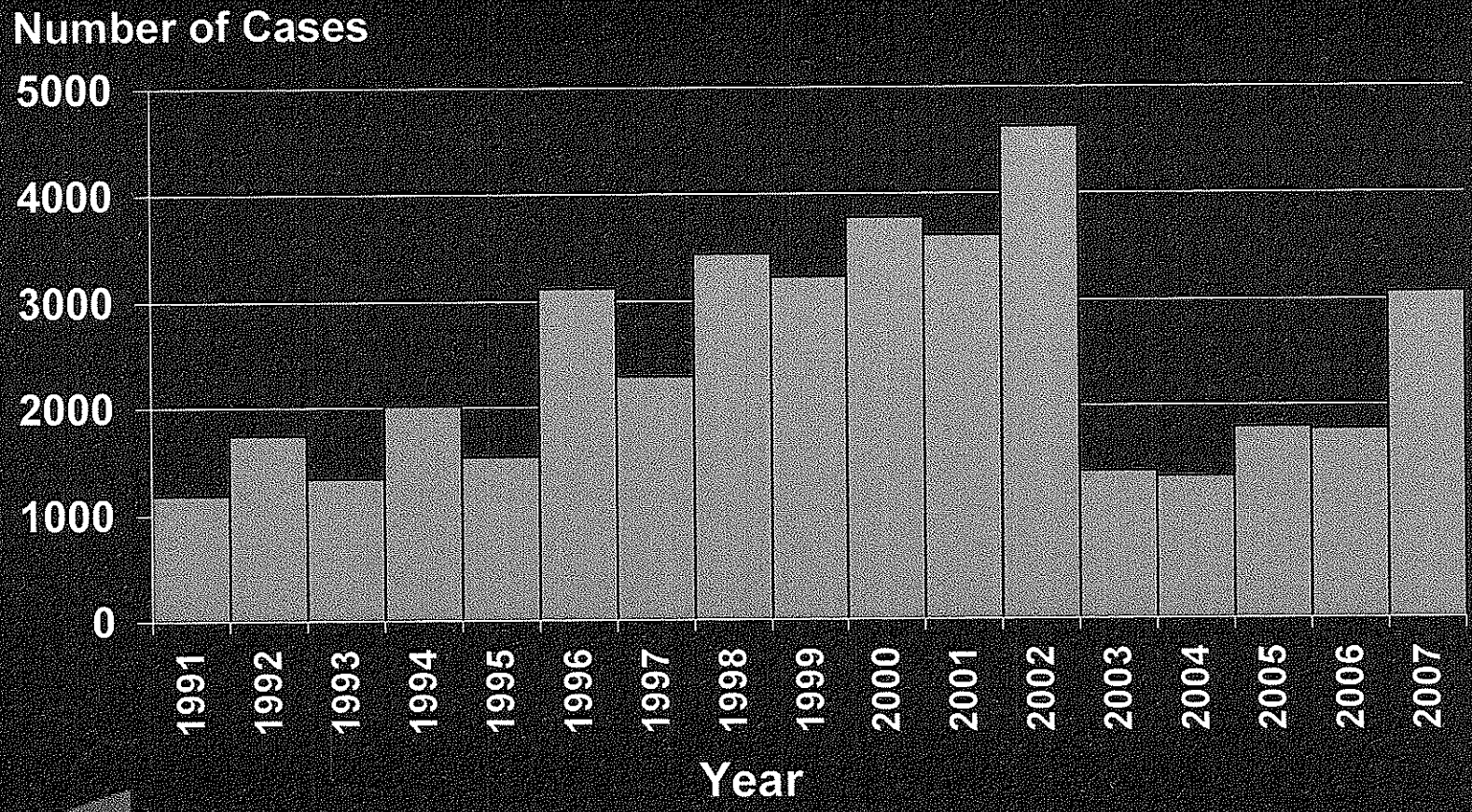
Lyme Disease Cases Statewide Connecticut, 1991 – 2007



** Drop in case numbers and rates after 2002 is due to a change in the reporting system. The data is not comparable to that prior to 2003. Increase in case numbers in 2007 is due to change in the reporting system.

Connecticut DPH

Lyme Disease Treatment Studies

No clinical studies have determined the optimal antibiotics or the optimal duration of treatment. Controlled clinical studies to date have been limited and conflicting, although two out of the three studies showed improvement on retreatment. Non-controlled studies also indicate that most patients improve with continued treatment. The controlled and non-controlled studies are described below.

Controlled studies of Persistent Lyme Disease			
Study	**Treatment**	**Results**	**Comments**
Cameron (2005) [1]	3 months treatment with amoxicillin	Treatment effective for 2/3 of patients with the worst quality of life as measured by SF-36	Results presented at ILADS 2005 Annual Conference.
Fallon (2004) [2]	10 weeks of IV Ceftriaxone	Cognitive improvement	Study in press, *Neurology*.
Krupp (2003)[3]	4 weeks of IV ceftriaxone	64% showed improvement on fatigue No improvement on cognition	Cognition finding criticized. Because subjects were not selected based on cognitive impairment, improvement on this scale would not be expected. There was insufficient statistical power to measure cognitive power.
Klempner (2001) [4]	4 weeks IV ceftriaxone then 2 months of oral doxycycline	No improvement on SF-36.	External validity of study criticized. The findings of this study's population sample (average 4.7 years ill and 3 treatment failures) lack generalizability to the clinical patient population.[5]

Despite the current focus on controlled studies, some researchers note that there is a high correlation between controlled and observational studies and that they "usually produce the same results".[6] In addition, non-controlled studies often provide more clinically-relevant treatment information because they deal with the diversity of patients seen in practice and allow for more flexibility in terms of treatment approach.

Non-Controlled Studies Supporting Longer Treatment Approaches or Retreatment	
Study	**Comments**
Oksi (1999) [7]	9 of 13 patients (69%) with disseminated Lyme disease who were initially treated for 3 months with oral or IV antibiotics but subsequently relapsed had good response to retreatment with IV ceftriaxone for 4-6 weeks. " [T]reatment... with appropriate antibiotics for even more than 3 months may not always eradicate the spirochete and long term antibiotics may be necessary."
Donta (1997) [8]	277 patients with chronic Lyme treated for between 1 and 11 months: 20% were cured, 70% improved and 10% had treatment failure.
Oksi (1998) [9]	30 patients with disseminated Lyme treated for 100 days, 90% with good or excellent responses: "prolonged courses of antibiotics may be beneficial in this setting".
Wahlberg (1994) [10]	Success rates for 100 patients with late Lyme disease: 31% (4 of 13) with 14 days of ceftriaxone; 89% (50 of 56) with ceftriaxone, then 100 days of amoxicillin and probenecid; and 83% (19 of 23) with ceftriaxone, then 100 days of cephadroxil.
Fallon (1999) [11]	18 patients retreated either with intravenous, intramuscular or oral antibiotics scored better on overall and individual measures of cognition. Those retreated with IV therapy showed greatest improvement.

The studies described above are necessarily limited to the choice of antibiotics tested and the duration that the antibiotics were given in the study. They do not tell us what would happen if patients were treated with different antibiotics or for longer periods of time. For a more detailed analysis of the treatment studies and treatment approaches, please refer to *Treatment of Lyme disease--a medicolegal assessment* [12] and *ILADS Evidence-based guidelines for the management of Lyme disease* [13].

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CT Attorney General

Connecticut Attorney General's Office

Press Release

Attorney General's Investigation Reveals Flawed Lyme Disease Guideline Process, IDSA Agrees To Reassess Guidelines, Install Independent Arbiter

May 1, 2008

Attorney General Richard Blumenthal today announced that his antitrust investigation has uncovered serious flaws in the Infectious Diseases Society of America's (IDSA) process for writing its 2006 Lyme disease guidelines and the IDSA has agreed to reassess them with the assistance of an outside arbiter.

The IDSA guidelines have sweeping and significant impacts on Lyme disease medical care. They are commonly applied by insurance companies in restricting coverage for long-term antibiotic treatment or other medical care and also strongly influence physician treatment decisions.

Insurance companies have denied coverage for long-term antibiotic treatment relying on these guidelines as justification. The guidelines are also widely cited for conclusions that chronic Lyme disease is nonexistent.

"This agreement vindicates my investigation -- finding undisclosed financial interests and forcing a reassessment of IDSA guidelines," Blumenthal said. "My office uncovered undisclosed financial interests held by several of the most powerful IDSA panelists. The IDSA's guideline panel improperly ignored or minimized consideration of alternative medical opinion and evidence regarding chronic Lyme disease, potentially raising serious questions about whether the recommendations reflected all relevant science.

"The IDSA's Lyme guideline process lacked important procedural safeguards requiring complete reevaluation of the 2006 Lyme disease guidelines -- in effect a comprehensive reassessment through a new panel. The new panel will accept and analyze all evidence, including divergent opinion. An independent neutral ombudsman -- expert in medical ethics and conflicts of interest, selected by both the IDSA and my office -- will assess the new panel for conflicts of interests and ensure its integrity."

Blumenthal's findings include the following:

- The IDSA failed to conduct a conflicts of interest review for any of the panelists prior to their appointment to the 2006 Lyme disease guideline panel;
- Subsequent disclosures demonstrate that several of the 2006 Lyme disease panelists had conflicts of interest;
- The IDSA failed to follow its own procedures for appointing the 2006 panel chairman and members, enabling the chairman, who held a bias regarding the existence of chronic Lyme, to handpick a likeminded panel without scrutiny by or formal approval of the IDSA's oversight committee;
- The IDSA's 2000 and 2006 Lyme disease panels refused to accept or meaningfully consider information regarding the existence of chronic Lyme disease, once removing a panelist from

the 2000 panel who dissented from the group's position on chronic Lyme disease to achieve "consensus";

- The IDSA blocked appointment of scientists and physicians with divergent views on chronic Lyme who sought to serve on the 2006 guidelines panel by informing them that the panel was fully staffed, even though it was later expanded;

- The IDSA portrayed another medical association's Lyme disease guidelines as corroborating its own when it knew that the two panels shared several authors, including the chairmen of both groups, and were working on guidelines at the same time. In allowing its panelists to serve on both groups at the same time, IDSA violated its own conflicts of interest policy.

IDSA has reached an agreement with Blumenthal's office calling for creation of a review panel to thoroughly scrutinize the 2006 Lyme disease guidelines and update or revise them if necessary. The panel -- comprised of individuals without conflicts of interest -- will comprehensively review medical and scientific evidence and hold a scientific hearing to provide a forum for additional evidence. It will then determine whether each recommendation in the 2006 Lyme disease guidelines is justified by the evidence or needs revision or updating.

Blumenthal added, "The IDSA's 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests -- in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies -- to exclude divergent medical evidence and opinion. In today's healthcare system, clinical practice guidelines have tremendous influence on the marketing of medical services and products, insurance reimbursements and treatment decisions. As a result, medical societies that publish such guidelines have a legal and moral duty to use exacting safeguards and scientific standards.

"Our investigation was always about the IDSA's guidelines process -- not the science. IDSA should be recognized for its cooperation and agreement to address the serious concerns raised by my office. Our agreement with IDSA ensures that a new, conflicts-free panel will collect and review all pertinent information, reassess each recommendation and make necessary changes.

"This Action Plan -- incorporating a conflicts screen by an independent neutral expert and a public hearing to receive additional evidence -- can serve as a model for all medical organizations and societies that publish medical guidelines. This review should strengthen the public's confidence in such critical standards."

THE GUIDELINE REVIEW PROCESS

Under its agreement with the Attorney General's Office, the IDSA will create a review panel of eight to 12 members, none of whom served on the 2006 IDSA guideline panel. The IDSA must conduct an open application process and consider all applicants.

The agreement calls for the ombudsman selected by Blumenthal's office and the IDSA to ensure that the review panel and its chairperson are free of conflicts of interest.

Blumenthal and IDSA agreed to appoint Dr. Howard A. Brody as the ombudsman. Dr. Brody is a recognized expert and author on medical ethics and conflicts of interest and the director of the Institute for Medical Humanities at the University of Texas Medical Branch. Brody authored the book, "Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry."

To assure that the review panel obtains divergent information, the panel will conduct an open scientific hearing at which it will hear scientific and medical presentations from interested parties. The agreement requires the hearing to be broadcast live to the public on the Internet via the

IDSA's website. The Attorney General's Office, Dr. Brody and the review panel will together finalize the list of presenters at the hearing.

Once it has collected information from its review and open hearing, the panel will assess the information and determine whether the data and evidence supports each of the recommendations in the 2006 Lyme disease guidelines.

The panel will then vote on each recommendation in the IDSA's 2006 Lyme disease guidelines on whether it is supported by the scientific evidence. At least 75 percent of panel members must vote to sustain each recommendation or it will be revised.

Once the panel has acted on each recommendation, it will have three options: make no changes, modify the guidelines in part or replace them entirely.

The panel's final report will be published on the IDSA's website.

ADDITIONAL FINDINGS OF BLUMENTHAL'S INVESTIGATION

IDSA convened panels in 2000 and 2006 to research and publish guidelines for the diagnosis and treatment of Lyme disease. Blumenthal's office found that the IDSA disregarded a 2000 panel member who argued that chronic and persistent Lyme disease exists. The 2000 panel pressured the panelist to conform to the group consensus and removed him as an author when he refused.

IDSA sought to portray a second set of Lyme disease guidelines issued by the American Academy of Neurology (AAN) as independently corroborating its findings. In fact, IDSA knew that the two panels shared key members, including the respective panel chairmen and were working on both sets of guidelines a the same time -- a violation of IDSA's conflicts of interest policy.

The resulting IDSA and AAN guidelines not only reached the same conclusions regarding the non-existence of chronic Lyme disease, their reasoning at times used strikingly similar language. Both entities, for example, dubbed symptoms persisting after treatment "Post-Lyme Syndrome" and defined it the same way.

When IDSA learned of the improper links between its panel and the AAN's panel, instead of enforcing its conflict of interest policy, it aggressively sought the AAN's endorsement to "strengthen" its guidelines' impact. The AAN panel -- particularly members who also served on the IDSA panel -- worked equally hard to win AAN's backing of IDSA's conclusions.

The two entities sought to portray each other's guidelines as separate and independent when the facts call into question that contention.

The IDSA subsequently cited AAN's supposed independent corroboration of its findings as part of its attempts to defeat federal legislation to create a Lyme disease advisory committee and state legislation supporting antibiotic therapy for chronic Lyme disease.

In a step that the British Medical Journal deemed "unusual," the IDSA included in its Lyme guidelines a statement calling them "voluntary" with "the ultimate determination of their application to be made by the physician in light of each patient's individual circumstances." In fact, United Healthcare, Health Net, Blue Cross of California, Kaiser Foundation Health Plan and other insurers have used the guidelines as justification to deny reimbursement for long-term antibiotic treatment.

Blumenthal thanked members his office who worked on the investigation -- Assistant Attorney General Thomas Ryan, former Assistant Attorney General Steven Rutstein and Paralegal Lorraine

Measer under the direction of Assistant Attorney General Michael Cole, Chief of the Attorney General's Antitrust Department.

View the entire IDSA agreement - (PDF-2,532KB)

Content Last Modified on 5/14/2008 8:40:39 AM

Lyme Organizations: New IDSA Guidelines Panel, Unbalanced & Biased
Congressman and Patient Groups Voice Concerns

Greenwich, CT, January 28, 2009-Patient groups voiced concern and disappointment about the new Infectious Diseases Society of America (IDSA) Lyme disease guidelines' panel, which excludes physicians who treat patients with chronic Lyme disease. Last May, the Connecticut Attorney General found the IDSA Lyme disease treatment guidelines' panel had conflicts of interest, engaged in exclusionary conduct, and suppressed scientific evidence. The investigation resulted in a settlement forcing the IDSA to reconstitute a balanced panel free of conflicts of interest under the oversight of an ombudsman to monitor conflicts of interest. No input from patients or treating physicians was permitted in selection.

"This situation is déja vu all over again," said national Lyme Disease Association president Pat Smith about the newly created guidelines' panel. "All Lyme disease treating physicians who applied for a seat were denied, based on having a "conflict" if they made over $10,000 treating Lyme disease. They have confused helping patients get better with 'real' competing conflicts such as interests in testing and vaccines, and relationships with insurers–a profile found in the original panel. Physicians who treat understand what makes patients well."

Attorney Lorraine Johnson of the California Lyme Disease Association points out "The problem is that guidelines conclusions generally reflect panel composition. That is why it is critical that a panel be balanced and include different points of view. Excluding the point of view of physicians who treat chronic Lyme disease makes no sense and biases this panel."

The current IDSA guidelines recommend against treating Lyme disease more than a few weeks, against using specific types of antibiotics, against alternative treatments and even supplements. The guidelines are so restrictive that physicians are not permitted to use clinical judgment in diagnosing or treating Lyme patients. The new panel will review controversial recommendations in the guidelines to determine whether there is sufficient scientific support for the recommendation.

According to Diane Blanchard, Co-President of Time for Lyme in Connecticut, "Treating physicians must be allowed to make clinical judgments about their patients' conditions due to the complexity of tick-borne diseases, and there are a number of physicians out there nationwide who are knowledgeable enough to recognize the effects of coinfections on diagnosis and treatment. Some have been treating for over 10-20 years and have tens of thousands of hours of experience seeing patients; yet, these physicians were not selected."

US Congressman Christopher Smith (NJ) co-chair of the House Lyme Disease Caucus, told the patient groups "The Settlement Agreement of the IDSA requires a balanced panel with a variety of experiences, including clinical experience in treating patients with Lyme disease. I share concerns raised about exclusion of physicians who treat persisting Lyme and the composition of the panel. I know I am joined by colleagues in Congress in the hope and expectation that the reassessment of the Lyme disease guidelines will be conducted with the highest levels of integrity and expertise. Nothing less will protect the rights and welfare of patients. We will continue to monitor this ongoing process."

The three groups are still hopeful, however, that the panel will take their responsibility seriously, since they have within their grasp the chance to improve the diagnosis and treatment for Lyme patients everywhere. Patients are counting on them to ensure that the weight of the science is evaluated fairly, which would be reflected in new standards that provide help for thousands of children and their families.

The groups feel patients should be provided with treatment options, including the use of long term antibiotics, to fight the disease, which has a disability equivalent to that of congestive heart failure. As in other areas where science is emerging, patients should have choices, and the exercise of clinical judgment by treating physicians should be encouraged. Studies of chronic Lyme disease show a failure rate of 26% to 50%, using the short-term antibiotic approaches currently advocated by IDSA.

ABOUT: The national Lyme Disease Association, (LymeDiseaseAssociation.org), the California Lyme Disease Association (lymedisease.org), and Time for Lyme (timeforlyme.org) are non-profit organizations that were founded by individuals who had personal experience with Lyme disease, in order to address the lack of education and support services available for this newly emerging infection.

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The Infectious Diseases Society of America Lyme Guidelines:

A Poster Child for Reform.

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Key Words: Lyme disease, IDSA, guidelines, evidence.

Financial Disclosure Statement: RBS serves without compensation on the medical advisory panel for QMedRx Inc. He has no financial ties to the company.

In their excellent review of medical guidelines (Jan 29, p. 429), Sniderman and Furberg describe specific problems with guideline development. The Lyme disease guidelines of the Infectious Diseases Society of America (IDSA) could serve as a poster child for these problems. The IDSA guidelines contain a disturbing number of 'evidence-based' recommendations (38 of 71) that depend on the weakest Level III evidence, namely 'expert opinion'. Consequently as outlined by Sniderman and Furberg, any irregularity in the guidelines panel that provided its 'expert opinion' becomes highly significant.

This concern prompted the Connecticut Attorney General to conduct an antitrust investigation into the IDSA Lyme guidelines development process (1). The Attorney General found that IDSA panel members had "commercial interests in drug companies and Lyme disease diagnostic test patents and consulting arrangements with insurance companies" and that IDSA failed to conduct a conflict of interest review for any of the panelists (1). The IDSA guidelines restrict the definition of Lyme disease and mandate controversial diagnostic testing (2-4). Guidelines that restrict a disease definition are favorable to vaccine manufacturers because they increase the apparent effectiveness of the vaccine. Guidelines that mandate diagnostic testing promote the interests of diagnostic test patent holders. Guidelines that deny treatment to patients are favorable to paid insurance company consultants. The Attorney General found that the IDSA Lyme guidelines panel members had commercial conflicts of interest in each of these areas (1).

The IDSA guidelines panel excluded divergent opinion that was available in peer-reviewed publications (2-4), failed to acknowledge treatment controversy, and denied treatment alternatives for patients and their physicians. The American Academy of Pediatrics recommends that when guidelines are based on "expert opinion", they should not displace the clinical judgment of treating physicians and they should provide treatment options (5). When guideline panels substitute their "expert opinion" for that of the treating physician and deny treatment options, the patient's right to autonomy—to choose among treatment alternatives--is foreclosed, and physicians who practice medicine using their best clinical judgment run the risk of censure for falling below the standard of care. Thus recommendations based on "expert opinion" must include divergent opinion and provide treatment alternatives.

As pointed out by Sniderman and Furberg, opinions are not science and should not be treated as such. Guideline reform is urgently needed to avoid opinion-based conflicts of interest, suppression of scientific evidence, blocking of divergent viewpoints and foreclosure of treatment options for patients.

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November 15, 2005

Senator Gibson Armstrong, Chairman
Senate Banking and Insurance Committee
281 Main Capitol Building
Harrisburg, Pennsylvania 17120

Re: H.R. 1534

Dear Senator Armstrong:

I am writing on behalf of the national Lyme Disease Association (LDA), the California Lyme Disease Association (CALDA) and The Pennsylvania Lyme insurance working task force to support PA House Bill 1534. While I have provided a point-by-point refutation to the issues raised by the Infectious Disease Society of America (IDSA) concerning that bill, I think it is important to look beyond the prestige and reputation of this organization to understand the true interests at play.

Between 72 and 90% of physicians writing clinical practice guidelines have undisclosed conflicts of interests.[1,2] These conflicts may arise from pharmaceutical, insurance, academic or research ties. It is the role of a specialty society to secure economic and career enhancing advantages for its members. However, unless medical societies are vigilant, it is easy for the goal of providing quality health care to the patient to become secondary to other economic goals of a guideline panel. The role these considerations may have played in the IDSA guidelines or in its approach to the treatment of chronic Lyme disease is unknown and under scrutiny. Clearly, it would be imprudent to rely unduly on the IDSA viewpoint on Lyme disease without exploring these issues. As Hurwitz stated in a recent critique of practice guidelines,

> *'However impressive the organization that sponsored the guidelines, or its process for developing them, the fact that a protocol exists for a particular condition does not mean that what it proposes is true. Nor does it guarantee that the protocol accurately represents customary practice... "[3]*

1. **Lyme disease economics are dominated by researchers interested in academic career advancement, diagnostic kits, and vaccines.** The *real* money in Lyme disease is in diagnostic kits or vaccines—not in treatment—and is controlled by researchers—not treating physicians. This economic reality is illustrated by the fact that pharmaceutical companies have not funded a single treatment study for Lyme disease (which is treated with off-label antibiotics), but have funded two vaccine trials, and academic institutions and the federal government have funded diagnostic kit research. The IDSA panel for its 2000 guidelines as well as its newly constituted guideline revision panel each consists primarily of researchers who have received federal research grants in excess of $20 million dollars and private grants of an undisclosed amount. These panel members devote a negligible amount of time to the actual treatment of patients with Lyme disease. Researchers may be more concerned with protecting their research turf, promoting agendas that advance their research interests, and expanding their professional sphere of influence, than with providing patients with the highest quality of care. Surely, there is a place for researchers on guideline panels, but panels which are unduly weighted by researchers may, as here, miss the fundamental goal of medicine—improving patient care. Moreover, the feedback loop between what researchers find in studies and what physicians find in treating patients in clinical practice is severed.

2. **Several of the panel members had undisclosed commercial conflicts of interest in vaccine trials, diagnostic kits, and insurance consulting.** A number of the IDSA guidelines panel members were compensated for running the failed vaccine trials by Connaught or SmithKline Beecham, or are known to hold commercial interests in Lyme diagnostic kits or patents. Kaiser, one of the largest HMOs in the nation, refers some of its Lyme blood work to a panel member's lab—a lab which is not accredited and which is well known for its high number of "negative" lab results. Some panel members receive consulting fees for drafting insurance guidelines or testifying on behalf of insurance companies. Patients seeking insurance coverage for chronic Lyme are routinely referred by their insurers to IDSA physicians for a "second" opinion and reimbursement may be contingent on treatment by an IDSA physician. . This means that members of the IDSA have a lock on the insurance business in the treatment of Lyme disease, which is pivotal given that insurance companies are the "economic" customer of health care services.

3. **Panel members who have been sued may not be sympathetic to patient interests.** Panel members involved in running the vaccine trials were named as defendants in the class action law suits by patients who were injured as a result of the vaccine. In addition, some panel members have had numerous complaints filed against them with their local medical boards. We have been informed that one of the items on the business agenda for the recent annual meeting of the IDSA, was to defeat patient legislative advocacy efforts by Lyme patients. This may be an appropriate goal for an insurance company—but for a medical specialty society it must raise questions. Generally speaking, medical societies do not view the patients as the problem. Here, the IDSA has squared off against patients, and its viewpoint and guidelines must be read in this light.

4. **The IDSA guideline panel was non-diverse and held well-known polemic viewpoints.** The Institute of Medicine recommends that guideline panels reflect a diverse range of viewpoints and perspectives to prevent the biased selection of evidence, skewed interpretation of evidence, or an idiosyncratic set of values. Although the IDSA itself is a large specialty organization with a reputation for excellence, the panel that drafted the guidelines was narrowly drawn and consisted almost exclusively of like-minded academic researchers with a corner on the research grant market. The panel members had well-known ideological views, representing one of the two schools of thought on treatment. When disagreement arose about the treatment of chronic Lyme disease, the dissenting member (widely published on the topic of Lyme disease with extensive experience treating patients) was purged from the panel, and a new chairman was selected to strong arm a consensus. The failure to disclose this dissension gave a false sense of uniform consensus where none existed. The IDSA is revising their treatment guidelines with yet another narrowly drawn panel of researchers. Although a number of groups, including the Lyme Disease Association (LDA), have asked the IDSA to expand its guideline panel to reflect the interests of patients and treating physicians, it remains to be seen whether the panel will ultimately embrace a less dogmatic viewpoint or continue with its high-handed approach. To date, the LDA's September 22nd letter remains unanswered.

5. **IDSA monopoly power sways physicians but not informed patients.** The IDSA is one of the most powerful medical societies in the world. When it promulgates guidelines, the majority of physicians adopt its protocols without question on the strength of its overall reputation. Despite the monopoly power wielded by the IDSA, few informed patients have been treated according to the recommendations stated in their guidelines, perhaps in part due to the fact that these guidelines have not changed fundamentally in over 20 years. This wide-spread defection from IDSA standards in terms of actual patient care is an incredible discrepancy—that one of the most powerful medical associations may sway uninformed physicians but be so out of step with clinical realities that the medically informed patient refuses to follow their protocols speaks volumes.

Patients with chronic Lyme disease suffer a degree of disability equal to that of patients with congestive heart failure[4]. These patients deserve more from our health care system than the denial of care that insurers and the IDSA advocate. Legislation is necessary to protect patients and practicing physicians

when an imbalance of power among the parties precludes equitable redress in the marketplace. This legislation insures that patients with chronic Lyme disease can obtain treatment, that insurers are accountable for providing that treatment, and that their doctors cannot be prosecuted for unprofessional conduct for providing longer term treatment. Given that the IDSA guidelines essentially provide for no treatment for patients with chronic Lyme disease, this legislation ensures that patients in need of medical care are not abandoned

If you have any questions or need additional information, please contact me at 323-461-6184 or Pat Smith, LDA president at (732) 938-4834.

Sincerely,

Lorraine Johnson, JD, MBA
Advisory Board, Lyme Disease Association
Executive Director, California Lyme Disease Association

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Senator Lisa Boscola
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Senator Christine Tartaglione
Senator Anthony Williams
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July 25, 2005

The Honorable Edward G. Rendell Pennsylvania State
Governor 225 Main Capitol Building
Harrisburg, Pennsylvania 17120

Re: IDSA Letter in Opposition to H.R. 1534

Dear Governor Rendell:

I am writing on behalf of the national Lyme Disease Association (LDA), the California Lyme Disease Association (CALDA) and The Pennsylvania Lyme insurance working task force to respond to the letter in opposition to PA House Bill 1534 submitted by the Infectious Disease Society of America (IDSA) The LDA with chapters and affiliates nationwide (including Pennsylvania) is a non-profit organization dedicated to Lyme disease research, education, prevention and patient support. CALDA is a non-profit organization that represents patients throughout California and publishes the *Lyme Times*, the only national publication that addresses Lyme disease and reaches over 10,000 patients. The Pennsylvania Lyme insurance working task force consists of professional members of several groups who are working with PA legislators on the insurance issue.

Our response to the primary points raised by the IDSA follows.

1. **The legislation is based on sound science and health care policy.** The IDSA claims that this legislation is inappropriate because the IDSA disagrees with the underlying science. There are two standards of care in the treatment of Lyme disease, both of which are reflected in peer-reviewed evidence-based guidelines posted on the National Guidelines Clearinghouse maintained by the US Department of Human Health Services.[1, 2] This legislation is not about resolving scientific disputes. It is about safeguarding the right of seriously ill patients to obtain treatment under one of the two conflicting standards of care. Moreover, a significant body of evidence supports the persistence of the bacteria underlying Lyme disease after short-term treatment as well as the efficacy of longer-term treatment approaches. (See attached tables.) Significantly, the Columbia/NIH Study, (completed last year with publication expected by year's end) found significant improvement on longer-term therapy. The studies include controlled studies as well as uncontrolled studies and case reports. Controlled studies are the exception rather than the rule for conditions perceived to be less common, like Lyme disease, which do not attract pharmaceutical research funding. In such cases, setting the evidence bar too high is tantamount is simply denying care to seriously ill patients.

2. **Antibiotic treatment is not harmful.** The IDSA asserts that antibiotic treatment *may be harmful.* However, the FDA Center for Drug Evaluation and Research found that a significant amount of data (including data on Lyme disease) support the safety of long-term antibiotic therapy.[3] More importantly, the risks of failing to treat this serious illness far outweigh any minimal risks associated with antibiotic treatment. Under the medical ethics principle of autonomy, patients, not medical specialty societies, are in the best position to decide if the "discomfort, inconvenience and expense" of treatment are outweighed by the risk of allowing a serious infection to progress untreated.

3. **Cost shifting is not cost saving.** The IDSA expresses concern over the costs of treatment. However, denying patients appropriate care does not save money, it merely shifts the burden to other medical and professional costs, like palliative care, increased doctors', emergency room, and hospital visits, educational accommodations, and social services for those unable to work. A recent article in Forbes reports on a study showing that the number of physician visits required to provide quality care for chronic conditions increases three fold when diseases are not well managed. [4]

4. **Human bacterial infections are an appropriate use of antibiotics.** Concern about the emergence of antibiotic resistance is laudable, but the IDSA's priorities are misplaced. Treating bacterial infections in humans is an appropriate and paramount use of antibiotics. This means that increasing hospital hygiene and decreasing the use of antibiotics to fatten livestock—the primary causes of antibiotic resistance--should be addressed first. The resistance issue for treating human bacterial infections is failure to treat to efficacy[5] (the very under-treatment the IDSA advocates).

5. **Most physicians consider all available evidence.** The IDSA's assertion that most physicians make decisions based on controlled studies misses the mark by a wide margin. All medicine is based on evidence (including non-controlled studies, case studies and individual patient response to treatment), but only a small portion of it is based on controlled studies. According to the Institute of Medicine (IOM), 51% of medical practices have weak or no supporting evidence and only 4% are supported by controlled studies.[6] Suspending treatment of patients pending definitive controlled studies is not feasible because, as the IOM states, "scientific evidence is not likely to exist for a great many of the combinations of clinical problems and characteristics that patients bring to clinicians in the real world." As it stands, the bulk of medical practice is about managing uncertainty in the absence of definitive research. This legislation permits physicians to do so.

6. **Legislative redress is appropriate here.** The IDSA claim that legislation should not be used to address medical controversies is contradicted by legislative history (e.g. breast cancer, prostate cancer, AIDs). Legislation is necessary to protect patients and practicing physicians when an imbalance of power among the parties precludes equitable redress in the marketplace. Normally, the interests of the insurers in denying payments to increase profitability is counterbalanced by the interest of pharmaceutical companies in marketing their product. In Lyme disease, all of the antibiotics used for treatment are off-label usage of old drugs and the relatively small demographic precludes pharmaceutical company research. The experience of the Lyme community nationwide is that insurers are unwilling to discuss the issue, review the evidence, or consider alternative approaches unless they are compelled to do so by legislative action. Instead, insurers use the surveillance criteria of the CDC to deny coverage despite the fact that the CDC admonishes insurers not to do so. A more responsive attitude by insurers would make mandated coverage unnecessary.

7. **The legislation represents the views of tens of thousands of patients and the physicians who treat them.** The IDSA correctly states that the legislation does not reflect their views—nor should it. The IDSA hardly needs legislative protection. This legislation insures that patients with chronic Lyme disease can obtain treatment, that insurers are accountable for providing that treatment, and that their doctors cannot be prosecuted for unprofessional conduct for providing longer term treatment. Given that the IDSA guidelines essentially provide for no treatment for patients with chronic Lyme disease, this legislation ensures that patients in need of medical care are not abandoned.

If you have any questions or need additional information, please contact either Pat Smith at _____ .

Sincerely,

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